additional concerns or conditions? So do we--well, that would be our working point for when and if there is a recommendation for approvable with conditions.

[Pause.]

CHAIRMAN McCULLEY: Normally what we do is someone would be scribing them, so she's just going to be typing them instead of us scribing them so everyone sees them so there is less opportunity for confusion. We get confused.

Now, okay. So it's a semi-point of order. I mean, are we going to--what we would be doing here, Malvina, as I understand it, we would--Malvina? What we would be doing here, as I understand it, would be listing what other conditions we thought should be on here in labeling conditions--or recommendations that we would put. That will presumably have an impact on what our conditions are. So we can do our recommendations--what our other recommendations for labeling would be now.

DR. EYDELMAN: Yes.

CHAIRMAN McCULLEY: Okay. And understand that these are not conditions, but they will affect what--if we have conditions on anything, what those conditions might be because we don't know what we're going to recommend yet.

Okay. So recommendations for additional labeling issues. Alice has been over here scribing. Do you think you could do it, or do we want to--Mike has them written out

in his. Do you want to list yours one at a time?

DR. GRIMMETT: Sure.

CHAIRMAN McCULLEY: But try to put them in as few words as possible that make the point, and no commentary on them.

DR. GRIMMETT: No commentary.

Information about subjective symptoms, worse and significantly worse categories should be included.

CHAIRMAN McCULLEY: Right. Write what he just said.

DR. GRIMMETT: Is there any objection to that recommendation from anyone on the panel?

CHAIRMAN McCULLEY: Include--symptom, patient symptoms, include both worse and significantly worse.

DR. GRIMMETT: And those can be separate categories. That would perhaps give the patient more information rather than lumped.

CHAIRMAN McCULLEY: Okay. Next one? Well, I guess as we go, is there disagreement with that?

[No response.]

CHAIRMAN McCULLEY: Okay.

DR. GRIMMETT: I would recommend including satisfaction and/or dissatisfaction data in the patient booklet. I was unable to locate that in the Patient Information Booklet.

CHAIRMAN McCULLEY: Okay. The satisfaction and significantly dissatisfied--or unsatisfied and--

DR. GRIMMETT: Unsatisfied and--

CHAIRMAN McCULLEY: There are two categories.

DR. GRIMMETT: Right.

CHAIRMAN McCULLEY: And I think they included only one, significantly dissatisfied. It's all--yes, dissatisfied and very dissatisfied. So include in the patient information, dissatisfied and very or significantly dissatisfied, both.

MS. NEWMAN: Make it subjective, not just all these numbers, okay? Make it so it's user--the consumer understands what you're saying when you say satisfaction, dissatisfied. Do you mean vision? Do you mean something else? Not just numbers or tables.

CHAIRMAN McCULLEY: Okay. Is there disagreement with this?

[No response.]

CHAIRMAN McCULLEY: Next?

DR. GRIMMETT: Analogous point regarding quality of vision, include worse and significantly worse categories. The same type of point. I don't know if you'd include quality of vision under patient symptoms. I think it's a separate category.

DR. MACSAI: No; separate.

CHAIRMAN McCULLEY: And significantly worse. Okay. Next, Mike? Is there disagreement with that?

[No response.]

CHAIRMAN McCULLEY: Next?

DR. GRIMMETT: I would recommend including a comment about the one in four rate of dryness, worse or significantly worse, happened in one in four.

CHAIRMAN McCULLEY: Those are both symptoms and signs.

DR. ROSENTHAL: May I just ask, what about in precaution? This issue of dryness--

CHAIRMAN McCULLEY: It's common after LASIK.

DR. ROSENTHAL: In everybody?

CHAIRMAN McCULLEY: Yes.

DR. ROSENTHAL: So what about people who preoperatively have dry eyes?

CHAIRMAN McCULLEY: They're going to be in worse shape.

DR. MACSAI: Treat them.

DR. ROSENTHAL: What?

DR. MACSAI: They should be screened and treated.

DR. ROSENTHAL: Well, I mean, you know, mild dry eyes. I don't know how we've dealt--I mean, I don't think it's relative to this LASIK procedure, but--

CHAIRMAN McCULLEY: It's not, and we're learning

more as time goes on. Now we know, so we don't want to ignore it. It's real. And it's probably important from a patient's information and informed consent to be certain that they're aware, because it can lead to sufficient dissatisfaction to seek attorney help.

DR. MAGUIRE: Especially when 45 eyes have punctate keratopathy persisting at 1 month postop, which is higher than what we see in the myopic group. A lot higher.

DR. GRIMMETT: Additionally, regarding the dryness, it's my belief, at least I think the sponsor stated in their protocol, that they excluded patients with severe dry eye at the outset. So I don't think they did operate on severe dry eye. Yes, that's correct. They're nodding affirmatively.

CHAIRMAN McCULLEY: Disagreement with that?

[No response.]

CHAIRMAN McCULLEY: Next?

DR. GRIMMETT: I would recommend changing the statement in the Patient Information Booklet on page 18 that said that patients did not lose best corrected visual acuity. Certainly some patients did lose two lines. It just requires clarification. I think it's misleading.

CHAIRMAN McCULLEY: Disagreement with that?

[No response.]

DR. GRIMMETT: Regarding induction of cylinder, I

would recommend including data in the labeling regarding a 1-diopter threshold rather than simply the 2-diopter threshold, and perhaps Dr. Maguire can amend that with other concerns that he stated at length earlier.

DR. MAGUIRE: I think--do we have information on induced cylinder in the simple hyperopic group? I'm not sure--I cannot recollect if there's a table on induced cylinder in the hyperopic astigmatism group or the mixed astigmatism group. And if they're not, it seems like FDA would want to know that and include that as well as this.

DR. YAROSS: Mr. Chairman, I would just suggest that, as FDA looks at that, they may want to look at what's been required of other sponsors so that labeling for various products is relatively similar, unless there is a specific safety issue.

CHAIRMAN McCULLEY: I don't recall us discussing this before, but also I don't recall us facing this degree of induction of astigmatism that we've been aware of.

DR. MACSAI: I also would comment this is a new indication.

DR. MAGUIRE: That's correct. And as Jim has said, patients who one would--as Dr. Salz has said, patients one would expect to have more optical complaints based on what we know about these ablation patterns seem to have less. So it may be that these people are willing to put up

with a lot more optical slop in the system than others, but not every--but we are going to have our obsessive-compulsive group that has this done, and they should be aware of this.

DR. GRIMMETT: Next, I would highlight the declining predictability when starting with preop spherical equivalent greater than 4.

CHAIRMAN McCULLEY: Disagreement with that?

DR. BRADLEY: Just a comment on that. Declining predictability--

DR. GRIMMETT: I mean achieving--

DR. BRADLEY: Patient friendly--

[Simultaneous conversation.]

CHAIRMAN McCULLEY: Fewest number of words that we can understand here.

DR. GRIMMETT: That was my intent. I meant plus or minus a half and plus or minus 1, blah, blah, blah.

CHAIRMAN McCULLEY: We're putting it into Americanese. This is okay for our purposes. Disagreement on this?

[No response.]

CHAIRMAN McCULLEY: Okay. Next, Mike?

DR. GRIMMETT: It is exactly the similar statement except for declining uncorrected visual acuity levels. It's the same idea, for those greater than 4 diopters.

CHAIRMAN McCULLEY: So it would be highlight the

declining predictability in--

DR. GRIMMETT: In uncorrected vision.

CHAIRMAN McCULLEY: UCVA.

DR. GRIMMETT: The intent on the first one is plus or minus a half or plus or minus 1, achieving--aimed versus achieved. The second one is just declining uncorrected visual acuity. It still goes under efficacy, I suppose.

CHAIRMAN McCULLEY: Okay. Disagreement on that?

DR. BRADLEY: I'm just wondering whether all those can be summarized as the efficacy will decline as the hyperopia or astigmatism increases.

DR. GRIMMETT: Sure. Patient may not exactly--that's true. That's a summary statement, but it has to include uncorrected vision as well as achieving those goals, plus or minus a half or plus or minus 1.

CHAIRMAN McCULLEY: Let's be sure. I think we do need to agree on which specifics we agree on, and then I think they probably do need to go into the labeling, and they can come under a heading as you're suggesting and Mike is. So no disagreement on that.

Next, Mike?

DR. GRIMMETT: I think my final labeling recommendation, depending on whether retreatment is going to be recommended or not, I believe the numbers are too low regarding retreatment outcomes. So I don't even know if the

labeling currently includes a comment on retreatment. But I would make a statement saying that insufficient data to analyze retreatment outcomes. Something to that effect.

CHAIRMAN McCULLEY: Okay. Safety and efficacy of retreatment.

DR. GRIMMETT: Are unknown. Safety and efficacy of retreatment are unknown.

CHAIRMAN McCULLEY: Ms. Newman?

MS. NEWMAN: You did say other things, though. You talked about race. I mean, do you have to put--

MS. THORNTON: Could you speak into the microphone, please?

MS. NEWMAN: It was only done in Caucasian, so this is only a white population. And do we want to say anything about age? You've got contraindications with, of course, cataracts and glaucoma, but, again, the age span, you need to state what this study was done in.

CHAIRMAN McCULLEY: Okay. Marian, you had that so succinctly in words to go up here, your caveat relative to age and sex.

DR. MACSAI: It would be to include the data on Table 1, Section A.4, page 9 of 20, regarding age, stratification of data for spherical corrections, astigmatic corrections, include information about outcomes in HRT and non-HRT women. That means hormone replacement therapy.

MS. NEWMAN: That table doesn't include race.

DR. MACSAI: No. But for the age, that's where--

CHAIRMAN McCULLEY: Well, basically the labeling has to indicate that it was a Caucasian population and 1.4 percent Hispanic.

MS. NEWMAN: Minorities--

CHAIRMAN McCULLEY: What?

MS. THORNTON: We can't get your comments, Diane, unless you use the microphone.

MS. NEWMAN: Just the race, the race issue. This was a study done in Caucasians. So we don't know what the effect is in race, and then like Marian said, the age issue and the hormone replacement.

CHAIRMAN McCULLEY: Okay. Agreement on this? Disagreement, I should say. Is there disagreement on this point?

[No response.]

CHAIRMAN McCULLEY: Other points? Okay. Alice has--she's been scribing here. What else?

DR. MATOBA: I think we covered almost all of it, but I just wanted to ask Mike: In your report, you made a point about the high rate of decrease in best corrected visual acuity two or more lines for the 4 to 5 and 5 to 6 diopter hyperopic astigmatic group. Did you want to add that specifically to the line up there?

DR. GRIMMETT: That was in the original stratification by manifest refraction spherical equivalent. The manufacturer did break that down or follow up those patients, and at least half of them went away within one line of preop best corrected visual acuity. So those--

DR. MATOBA: So you want to leave it like just include that in page 18 regarding loss and not be any more specific.

DR. GRIMMETT: Yes, I probably would--

DR. MACSAI: I would include it. I think it's important to include not just the loss of greater than, but greater than or equal to two lines BSCVA.

DR. MATOBA: Do you want to amend that number three up there?

DR. MACSAI: And not just in the patient information but also in the doctor's information.

DR. MATOBA: To be more specific, or not?

DR. MACSAI: I think they know what we mean.

DR. ROSENTHAL: We know.

DR. MATOBA: The only other thing was that Jose Pulido said something about dealing with regression analysis. That was that comment that--

DR. PULIDO: That was age and--

DR. MATOBA: Age? That's taken--okay.

CHAIRMAN McCULLEY: So your point is taken care

of?

DR. MATOBA: Right.

CHAIRMAN McCULLEY: Leo and then Marian.

DR. MAGUIRE: I think there should be a comment that people who lose two or more lines of best corrected visual acuity are more likely to have an unstable refraction during the first year or the first 6 months, or whatever the time periods are, based on comments I made earlier about changes in the 16 of 55 eyes in that one table.

CHAIRMAN McCULLEY: That's a tricky labeling issue. Can we ask the FDA to take that under advisement? You need to put it up there. A few words, Leo, that would trigger the thoughts for them.

DR. MAGUIRE: Okay.

DR. ROSENTHAL: Those eyes that lost two or more lines BSCVA would be useful.

CHAIRMAN McCULLEY: Okay. Can you put that?

DR. MAGUIRE: Refractive instability is increased in patients who--

CHAIRMAN McCULLEY: Start over.

DR. MAGUIRE: Okay. Refractive instability--

CHAIRMAN McCULLEY: No, I'm talking--she needs to get it backed up. Just a second. I'm talking to Quynh.

DR. MAGUIRE: Refractive instability increases--it should be risk of refractive instability increases in

patients who lose two or more lines best corrected vision.

CHAIRMAN McCULLEY: Is there disagreement with that?

DR. YAROSS: Just a comment, if I may. What you have there are one outcome saying--being dependent on another outcome.

DR. MAGUIRE: That's correct.

DR. YAROSS: It's not predictive in terms--so it may be--if there's a way to turn that into something predictive, it may be more useful in labeling. I'm not sure--

DR. EYDELMAN: We'll work on the language.

CHAIRMAN McCULLEY: What I said before was this is a tricky labeling issue, we'll ask the FDA to take that under advisement, and they have our thoughts there.

Other--Marian?

DR. MACSAI: I'd like to see the retreatment rate included in this study cohort.

CHAIRMAN McCULLEY: Give us words.

DR. MACSAI: It looked to me there was a 10 percent re-op rate.

CHAIRMAN McCULLEY: What's wrong with that?

DR. MACSAI: No, I want that to be included. It's--

DR. ROSENTHAL: Dr. Macsai, it always is.

DR. MACSAI: I know it is, but--

DR. ROSENTHAL: This is in our final labeling, but we appreciate the suggestion.

DR. MACSAI: Okay.

DR. ROSENTHAL: But it is mandatory.

DR. MACSAI: All right.

CHAIRMAN McCULLEY: Jan?

DR. JURKUS: I think something in terms of monovision patients can expect to wear glasses while driving at night should be included.

CHAIRMAN McCULLEY: I'm not sure I agree with that.

DR. JURKUS: That's what was stated when we talked today that--

CHAIRMAN McCULLEY: Often they do. But--

DR. SUGAR: We don't have the data on that.

CHAIRMAN McCULLEY: Yes, I'm not sure how that would go in labeling. That's part of informing the patient, and as Jim Salz said, anyone who does it without putting them into contact lenses up front to know they're going to like it is probably a fool. I'm not--Marian?

DR. MACSAI: I guess what I'd also like to see included in the physician's handbook is something about the fact that the TZ goes to 9 millimeters. So it would be in the interest of the surgeon to select a keratome that cuts a

9 millimeter flap, not 8.5.

CHAIRMAN McCULLEY: Is that something that really-

DR. MACSAI: Well, in the study they--

CHAIRMAN McCULLEY: In the study they--you know, I think--some of these corneas are small, I imagine, is the reason they used 8--you know, allowed 8.5.

DR. MACSAI: You'd be surprised.

CHAIRMAN McCULLEY: I mean, that's going to be--well, okay. You're saying that we need to try to educate. That should be in the physician indication manual.

DR. MACSAI: That's right.

CHAIRMAN McCULLEY: Okay. Any other issues? Alice, did we get everything?

DR. MATOBA: In labeling or otherwise?

CHAIRMAN McCULLEY: Labeling first. Okay. Any other labeling issues? What otherwise did we bring up that we had?

DR. MATOBA: Mike Grimmett said he wanted endothelial cell counts after re-ops. I don't know if we decided formally whether we're going to--

DR. GRIMMETT: Well, sure, I'd love that. I just don't think that there's sufficient data available. And I think we covered it by saying that there's just insufficient data for retreatments. I think that would suffice.

DR. MATOBA: Okay.

CHAIRMAN McCULLEY: Was there anything else?

DR. MATOBA: Visual acuity at 1 week, Dr. Maguire.

CHAIRMAN McCULLEY: Yes, the patient functionality in the early time after lasering. That would be a label issue, that there needs to be adequate information so that the patients know what impact the procedure's going to have on their vision and their functionality in the early postop period.

DR. MAGUIRE: And, Jim, on top of that, I don't know if this is the appropriate time to ask if that is one thing that should go into postmarket approval study or not. We don't really know what the variation in patient satisfaction or discomfort and all those things are. Forget that. Strike it. Just if we could have--if we could have something--there should be information on loss of best corrected visual acuity at 1 week postop as well as at 1 month.

CHAIRMAN McCULLEY: They have 1-day and 1-week data, I'm sure. And what we're saying is that in the labeling there needs to be information for the patient so that they know what to expect in terms of vision and functional vision in the early period postoperatively. And I'm sure you have that, or you ought to.

DR. MACSAI: Can I expand that indication to be both the patient and physician booklets?

DR. ROSENTHAL: Yes.

DR. MACSAI: To help with the decision of unilateral versus bilateral treatment.

CHAIRMAN McCULLEY: Sure. I mean, that's important information that everyone needs to know.

Okay. Other--did I get everything else?

DR. MATOBA: Well, I think Dr. Grimmett had some concerns about the 3 to 3.99 diopter cylinder group having poorer results than other subgroups, and I think Dr. Macsai said the same thing and you said--did you want to ask for additional information?

DR. ROSENTHAL: Well, but we're talking about--these are labeling. You're getting--

DR. MATOBA: Oh, I thought we were beyond labeling.

DR. ROSENTHAL: Where are you now, Dr. McCulley?

CHAIRMAN McCULLEY: Where we are is, in going through, Alice made lists of all the concerns that came up, and probably what--

DR. ROSENTHAL: Well, could we finish the labeling and then go on to the condition--

CHAIRMAN McCULLEY: If there are any other concerns? I thought that one, to me, was adequately addressed, that we're dealing with a biological system, that ain't nothing perfect, things vary, and it's bracketed by

good data, and the numbers are small.

Does anyone else have any other--we're just making, you know--okay. So at this point, is there any further panel discussions on this PMA at this point? The order of things will be open public hearing. FDA has five minutes for closing comments, and the sponsor has five minutes for closing comments. And then we'll go into the formal aspects of voting with Sally starting off by reading the voting options to us and so on.

No further panel comment?

[No response.]

CHAIRMAN McCULLEY: Does FDA have closing comments? You have up to five minutes.

DR. ROSENTHAL: Just to thank you all very much for your--

CHAIRMAN McCULLEY: Wait until it's over. I'm sorry. Open public hearing. We'll now officially open the open public hearing session. Is there anyone in the audience who is public who wishes to come forward and make a comment?

[No response.]

CHAIRMAN McCULLEY: Seeing none, the open public hearing session is closed.

Now, does FDA have closing comments? None?

DR. EYDELMAN: No, sir.

CHAIRMAN McCULLEY: Sponsor has up to five minutes for closing comments if you wish.

MS. McGARVEY: Shirley McGarvey, regulatory consultant to ATC. We'd like to thank the panel for all of this discussion today. A lot of the activity today focused on guidance and changes to the guidance. We encourage that industry, the profession, and the FDA, again, work collaboratively as we look at improvements to the current guidance document and that we all can identify what should be in these labeling, particularly as these are first-of-a-kind indications.

Thank you very much.

CHAIRMAN McCULLEY: Thank you.

All right. Ms. Atherton will now reading the voting options?

MS. THORNTON: Who is Ms. Atherton?

[Laughter.]

CHAIRMAN McCULLEY: I do that every time. Thornton. Sally Atherton is--I'll tell you who she is later.

[Laughter.]

CHAIRMAN McCULLEY: Ms. Thornton. I don't know why I do that. I thought I was going to get through today without doing it.

MS. THORNTON: I hope she's a nice person.

DR. PULIDO: She tells a lot of dirty jokes. She's fine. She's the Chairwoman of the Department of Anatomy and Cell Biology at Medical College of Georgia.

MS. THORNTON: Okay. Thank you.

CHAIRMAN McCULLEY: Who just moved from University of Texas-San Antonio.

MS. THORNTON: She doesn't look a bit like me, I'm sure.

CHAIRMAN McCULLEY: No. But she has the same first name. Go ahead.

MS. THORNTON: That's no excuse.

CHAIRMAN McCULLEY: I thought I was going to get through the day without doing that.

MS. THORNTON: First of all, I'd like to read the panel recommendation options for the PMA, and then I think Dr. McCulley is going to talk to the panel about the procedures for voting before he calls for a motion.

The Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act as amended by the Safe Medical Devices Act of 1990 allows the Food and Drug Administration to obtain a recommendation from an expert advisory panel on designated medical device premarket approval applications, or PMAs, that are filed with the agency. The PMA must stand on its own merits, and your recommendation must be supported by safety and effectiveness data in the application or by

applicable publicly available information.

Safety is defined in the act as reasonable assurance based on valid scientific evidence that the probable benefits to health under conditions on intended use outweigh any probable risks.

Effectiveness is defined as reasonable assurance that in a significant portion of the population, the use of the device for its intended uses and conditions of use when labeled will provide clinically significant results.

Your recommendation options for the vote are as follows:

Number one, approval, if there are no conditions attached;

Number two, approvable, with conditions. The panel may recommend that the PMA be found approvable subject to specified conditions such as patient or physician labeling, labeling changes--I'm sorry, such as physician or patient education, labeling changes, or a further analysis of existing data. Prior to voting, all of the conditions should be discussed by the panel.

Number three, not approvable. The panel may recommend that the PMA is not approvable if the data do not provide a reasonable assurance that the device is safe or if a reasonable assurance has not been given that the device is effective under the conditions of use prescribed,

recommended, or suggested in the proposed labeling.

Following the voting, the Chair will ask each panel member to present a brief statement outlining the reasons for their vote.

Now you're going to talk about that chart.

CHAIRMAN McCULLEY: Okay. Our options at this point, we're going to call for a motion. It will be seconded. It will be discussed. And we can either have a motion for approval, we have a motion for not approvable, or we can have a motion for approvable with conditions. And we do not discuss the conditions at this point.

After the motion and the second, we then discuss additionally, and if there are conditions, we will vote on the conditions one at a time. And presumably that could be the list of labeling issues.

Dr. Pulido?

DR. PULIDO: I would like to motion approvable with conditions.

CHAIRMAN McCULLEY: Is there a second?

DR. MAGUIRE: Second.

CHAIRMAN McCULLEY: Is there any discussion further on the motion for approvable with conditions?

[No response.]

CHAIRMAN McCULLEY: All in favor of the motion as stated--no?

MS. THORNTON: If you want to go ahead and--

CHAIRMAN McCULLEY: Don't do that? Okay. All right. Sorry. So what we now do is discuss whether we're going to have conditions or not, and presumably--I mean, this thing doesn't flow real well, actually. We will discuss whether we want conditions, and we'll vote on the conditions--we'll vote the conditions up or down. Once we have the agreed-upon conditions, then we'll vote on the motion with the agreed-upon conditions.

MS. THORNTON: You all have these charts in your folders, and you will amend the main motion for each condition.

CHAIRMAN McCULLEY: Yes. In actual fact, these blocks just don't--I don't think they flow logically. But, anyway, so we now have a motion that's been seconded for conditions. We will now take the proposed conditions as amendments, and we will vote on each one as we go through.

MS. THORNTON: And they will be put up on the screen as you--when you've completed your voting on them, each one.

CHAIRMAN McCULLEY: Can we see our recommendations for labeling change?

DR. BRADLEY: Jim, could we summarize those as the condition being that the labeling be modified in accordance with this list of--

CHAIRMAN McCULLEY: We can--if we agree on all of these, I think we can do that.

DR. BRADLEY: Well, that's what we would vote on, whether we do agree.

CHAIRMAN McCULLEY: Well, I guess what we need to do, I think at this point the discussion would be whether this is what we would want, we would want to convert our recommendations to the recommended--or, you know, our suggestions here to the conditions.

DR. GRIMMETT: Dr. Bradley made a motion, include labeling recommendations as a condition. So we need to hear a second on that and then vote on that. Right? So I second Dr. Bradley's motion.

CHAIRMAN McCULLEY: All right. Further discussion?

Point of clarification is that you are recommending as the condition all of the things we listed in our recommendations for labeling before?

DR. BRADLEY: That is correct.

CHAIRMAN McCULLEY: Okay. So with that clarification of his motion, and you accept that as seconding that clarified, is there further discussion?

DR. MACSAI: We vote on each condition individually?

CHAIRMAN McCULLEY: No. He's putting them

together. That's why I was going a little bit differently. These are labeling. This list, one condition is change in labeling as we have recommended before, that list staying intact. So the question is--there are two questions. Are there any changes to that list? And if not, then we would be voting on that list in its entirety. Is there any discussion about the list of recommendations here that would become our labeling conditions?

[No response.]

CHAIRMAN McCULLEY: None? All in favor of the motion, raise your hand.

[A show of hands.]

CHAIRMAN McCULLEY: Opposed?

[None opposed.]

CHAIRMAN McCULLEY: Other conditions?

DR. ROSENTHAL: The indications, Mr. Chairman. Is that not a condition?

CHAIRMAN McCULLEY: Yes, we need to go back--where we have that I guess would be in the questions the FDA has posed to us, that we need to convert our answers to that to conditions.

So, Mike, would you like to start with--or Joel? We had recommendations for--the condition was on range.

DR. SUGAR: The condition was that the range be approved as requested pending receipt of 9-month data that

is deemed by the agency as adequate.

CHAIRMAN McCULLEY: Good motion. Is there a second to the motion?

DR. MACSAI: Second.

CHAIRMAN McCULLEY: Discussion?

[No response.]

CHAIRMAN McCULLEY: All in favor of the motion, signify by raising your hand.

[A show of hands.]

CHAIRMAN McCULLEY: Okay, that's seven. Opposed?

[A show of hands.]

CHAIRMAN McCULLEY: One. Did that cover all of the prior conditions? Oh, we're doing these conditions-- okay. Joel, will you help her with the wording here?

DR. SUGAR: That says it. Full range to receipt of 9-month data deemed by the agency to be appropriate.

CHAIRMAN McCULLEY: Are there any other conditions? Did we cover everything, Malvina, in your questions?

DR. EYDELMAN: Stratify patient symptoms, but that's in a way under labeling.

CHAIRMAN McCULLEY: Okay. Any other conditions? Dr. Matoba?

DR. MATOBA: I'd like more information, long-term information on the re-op patients, that is, 6-month follow-

up data on the patients they already have treated in terms of stability and their satisfaction.

CHAIRMAN McCULLEY: We basically said already in our labeling that we don't think that there's sufficient data to comment on retreatment, so I think we've kind of covered ourselves on that one.

DR. MACSAI: No.

CHAIRMAN McCULLEY: Have we not?

DR. MACSAI: It's different. One's labeling. This is a condition of approval. And Alice is asking for 6-month follow-up on retreated patients--correct?

DR. MATOBA: Yes.

DR. MACSAI: That's what she's asking for.

CHAIRMAN McCULLEY: Okay. I don't think that fits.

DR. MACSAI: Whether you want it or not, that's what she's asking for as a condition--

CHAIRMAN McCULLEY: Okay. Thank you.

DR. MACSAI: --of approval.

CHAIRMAN McCULLEY: Okay, okay. Is that a motion?

DR. MATOBA: Yes.

CHAIRMAN McCULLEY: Is there a second to that motion?

DR. MACSAI: Second.

DR. EYDELMAN: Can I clarify?

CHAIRMAN McCULLEY: Yes, you can.

MS. THORNTON: Now that we've seconded, you can--

DR. EYDELMAN: I'm just trying to understand what exactly the motion is. You're trying to say that you do not want this PMA approved until the 14 eyes that underwent retreatment--

DR. MATOBA: No, no. Just post-approval--I don't know the term, surveillance or--just collect that data after approval. It's not a condition--let's see.

DR. EYDELMAN: It's not a condition of approval, then.

CHAIRMAN McCULLEY: No.

DR. MATOBA: Okay. I withdraw it. I withdraw it.

CHAIRMAN McCULLEY: Any other conditions?

[No response.]

CHAIRMAN McCULLEY: All right. We now have a motion on the floor that's been seconded for approval with conditions that relate to labeling changes as listed, that the full range of requested approval will be pending based on 9-month data to be evaluated by the FDA--

MS. THORNTON: Excuse me. Dr. Rosenthal?

DR. ROSENTHAL: I just wanted to assure Dr. Matoba that the labeling would include the most updated data regarding the retreatment. Patient labeling.

CHAIRMAN McCULLEY: Dr. Rosenthal, you're out of

order, and I know she did it to you. We have a motion on the floor that's been seconded, and the motion is for approvable with--what?

MS. THORNTON: I'll explain it to you later.

CHAIRMAN McCULLEY: --conditions that labeling changes listed above that we have listed and that the full range to be approved pending 9-month data deemed to be appropriate or acceptable by the FDA.

Further discussion on the motion?

[No response.]

CHAIRMAN McCULLEY: All in favor of the motion, signify by raising your hand?

[A show of hands.]

CHAIRMAN McCULLEY: Eight. All opposed?

[No response.]

CHAIRMAN McCULLEY: Eight to nothing. Eight to nothing for approvable with those two conditions, as I stated them. That's the final vote.

Each panel member is requested to state why you voted as you did, and we will start with Dr. Pulido and come this way.

DR. PULIDO: Jose Pulido. I voted approvable with conditions. I had great concerns about the efficacy with age, and that being in the labeling, that was taken care of, and I think the sponsor should be congratulated on a well-

done proposal.

DR. MACSAI: I voted approvable with conditions. My concerns regarding age, hormone replacement therapy, loss of best corrected visual acuity, induced astigmatism, and early recovery of vision are addressed in labeling changes.

DR. SUGAR: Joel Sugar. I voted for approvable with conditions and agree that the conditions we have listed are appropriate and other issues have all been addressed.

DR. GRIMMETT: Michael Grimmett. I voted approvable with conditions based on my lengthy statements before. Additionally, I was pleased to see the sponsor provide follow-up data regarding those patients who lost best spectacle corrected visual acuity. I still have concerns regarding the low number of eyes in the stratified subgroups, limiting our ability to make firm conclusions. However, I believe the material submitted is reasonable for safety and efficacy.

DR. MATOBA: Alice Matoba. I voted for approvable with conditions, and my reasons are very similar to those of Dr. Macsai.

DR. MAGUIRE: Leo Maguire. Approvable with conditions. This is relatively safe, relatively effective, but there's still a difference in a significant minority of patients between expected and achieved cylinder and standard hyperopia which brings in a question, the overall spectrum

of treatment, and I certainly hope that in future studies we see more aberrometry data and get an idea if, in fact, there's significant variations in optical aberration, higher order aberrations in these people so we can start to get some sense that people can be happy with the result, think they're functioning well, but still be a danger to people on the road that they interact with, especially at night.

DR. BRADLEY: Arthur Bradley. I voted to approve with these conditions. I think the sponsor did an excellent job of demonstrating overall safety and efficacy and meeting the FDA guidance guidelines. The conditions are important, particularly the labeling ones, because I believe there are certain types or groups of patients who are not going to meet the overall expectations of the group, and by including those in the labeling, I think we've taken care of that problem.

DR. JURKUS: Jan Jurkus. I voted approvable with conditions because I believe the data showed that the benefits of this device outweigh the risks to the patients in this population.

CHAIRMAN McCULLEY: Thank you. Before adjournment, Sally has a few concluding comments.

MS. THORNTON: Ms. Atherton will now address the public.

At the end of the meeting, I am supposed to

announce to you that we are having a meeting May 11th and 12th, and it has just been decided that it will be at the Gaithersburg Hilton. So we'll see you there.

I'd like to remind the panel members to please leave all materials that they've been sent on the table for collection. You are accountable for anything that's missing.

And I'd also like to ask you to please take the little items that you don't want anymore and put them in the containers that have been provided for you. That doesn't include anything that should be left on the table.

CHAIRMAN McCULLEY: The meeting is adjourned.

[Whereupon, at 3:34 p.m., the meeting was adjourned.]

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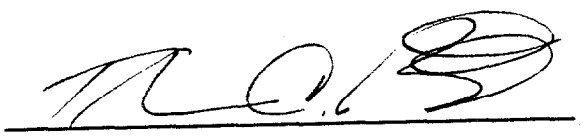
CERTIFICATE

I, **THOMAS C. BITSKO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



THOMAS C. BITSKO